

CHARLES E. SCHUMER
NEW YORK

United States Senate

WASHINGTON, DC 20510

July 7, 1999 7 0 2 3 '99 JUL 15 P2:22

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, Maryland 20857-0003

Dear Sir/Madame:

I am writing on behalf of my constituent, Ms. Kathleen Karlsen, 717 Castle Creek Road, Binghamton, New York 13901. She has contacted me regarding her efforts to receive a response from your office.

It is my understanding that Ms. Karlsen wrote to your office to express her concern regarding restrictions on patients obtaining prescribed medication. She states that she would like to see the Memorandum of Understanding modified.

Enclosed you will find correspondence from Ms. Karlsen, which is self-explanatory. Thank you for your cooperation and attentive reply to this matter.

Sincerely,


CHARLES E. SCHUMER
United States Senate

CES/ca

26 Federal Plaza
Suite 31-100
New York, New York 10278

98N-1265

C8783

5-18-99

Dear Governor Schomer-

A note to let you know
that I am concerned about being
able to get proper medication because
of the MOU which would make it
impossible for me to get it - as I
order it out of state and it is
compounded. There is nothing else
that will work for me - as I
have tried everything,

Please see the attached
copy of my letter to to FDA.

Thank you for your attention
to this matter.

Sincerely,

Kathleen Karlson
717 Castle Creek Rd,
Binghamton, NY 13901

(607) 648-6096

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Signed: _____

Kathleen P. Karlsen

State of Residence: _____

New York State

United States Senate

WASHINGTON, DC 20510-3203

OFFICIAL BUSINESS

Charles E. Schumer
U.S.S.

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